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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,117	11/30/2000	Robert G. Arther	MO 6049	2400
71285	7590	11/01/2007		
BAYER HEALTHCARE LLC			EXAMINER	
P.O.BOX 390			QAZI, SABIHA NAIM	
SHAWNEE MISSION, KS 66201			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			11/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/727,117

Applicant(s)

ARTHER, ROBERT G.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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### **Final Office Action**

Claims 21-23 are pending. No claim is allowed at this time. Amendments are entered.

### **Summary of this Office Action dated Thursday, October 25, 2007**

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. Double Patenting Rejection
5. 35 USC § 103(a) Rejection
6. Response to Remarks
7. Conclusion
8. Communication

**Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

**Copending Applications**

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

**Specification**

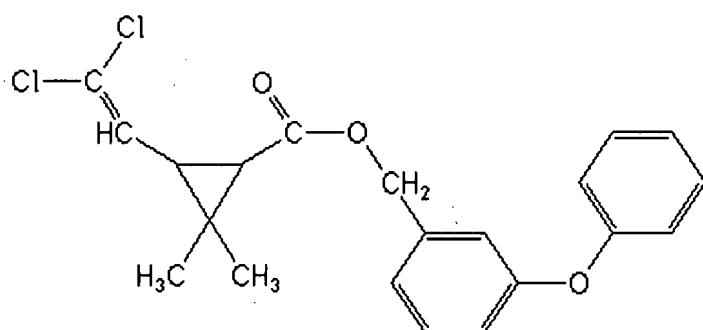
The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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### Restriction

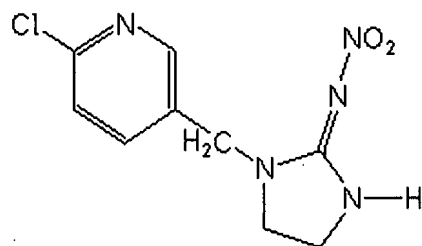
As per restriction requirement Applicant elected without traverse the claims directed to the combination specific pyrethroid and chloronicotinyl: permethrin and imidacloprid, respectively.

#### Permethrin



and

#### Imidacloprid



### Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

*A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).*

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23 provisionally rejected under the judicially created doctrine of double patenting over claims 8-12 of copending Application No. 10/682127 (Hereinafter SIRINYAN et al). This is a provisional double patenting rejection since the conflicting claims have not yet been patented. These applications share a common assignee.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: SIRINYAN et al is drawn to skin-friendly dermally applicable liquid formulations comprising permethrin and imidacloprid for the method of controlling fleas and/or ticks on "warm-blooded animals." The presently claimed invention is drawn to a process for treating a mammal infected

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with acarids (fleas or mites) comprising dermal administering to the mammal an effective amount of a composition comprising permethrin and imidacloprid.

It would have been obvious to one skilled in the art at the time of invention because warm-blooded animals, as in SIRINYAN et al, is the same as mammals, as in the presently claimed invention. All the ingredients listed in co-pending application are not cited in the present claims however the term comprising allows other ingredients to be added.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

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Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**Claim Rejections - 35 USC § 103---1<sup>st</sup> Rejection**

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn et al. (US Patent 6,232,328).

Dorn et al. teach the combination of pyrethroid and nicotinylic compound specifically imidacloprid and permethrin for the control of parasitic insects such as fleas, lice and flies, which embrace presently, claimed invention. See the entire document especially lines 8-10 and lines 35-68 in col. 17; lines 21 and 22 in col. 18; lines 5-10, lines 25-30 in col. 1; lines 5-10 in column 17 and lines 21 and 22 in column 18. Imidacloprid is disclosed in lines 20-25 column 4 and permethrin which is 3-phenoxybenzyl(+.-)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate, is particularly disclosed in lines 21 and 22 in column 18. The reference further teaches that active compounds can be present in the form of a mixture with synergists or other active compounds. The active compounds include natural or synthetic pyrethroids.

Instant claims differ from the reference in that they are of different generic scope. It had been decided by Courts that the indiscriminate selection of "some" from among "many" is considered prima facie obvious. *In re Lemin*, 141 USPQ 814 (1964); National



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Distillers and Chem. Corp. V. Brenner, 156 USPQ 163. Claim 22 differs from the reference in claiming specific ranges.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

It would have been obvious to one skilled in the art at the time of invention to prepare additional beneficial composition for controlling insects because prior art teaches control of insects by the same combination of compounds as taught by the prior art. Since the synergistic combination is taught by the prior art therefore there is a motivation to prepare the formulation for controlling insects.

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Dorn et al. teaches the combination of pyrethroid and nicotinylic compound for the control of parasitic insects such as fleas, lice and flies. Furthermore, it also teaches that the active compounds can be present in the form of a mixture may be synergists or other active compounds such as pyrethroids etc., see lines 5-10 in col. 17.

The ratio and combination would have been a routine experimentation because it was known that synergism exist between these compounds as taught by the prior art.

The present specification discloses the combination of a pyrethroid and a chloronicotinyl insecticide which provides enhanced activity against ticks and mites, while maintaining the activity of chloronicotinyl compounds against flees", (lines 20-23 on page 3). Synergistic effect of the combination with chloronicotinylic (imidacloprid) and pyreththroid (permethrin) is disclosed. Since prior art teaches synergistic effect of such combinations, one skilled in the art would expect synergism with any combination such as imidacloprid and permethrin, which are active compounds and has been presently claimed.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 103---2<sup>nd</sup> Rejection***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirinyan et al (US Patents 6,001,858).

Sirinyan et al. US '858 teaches the combination of imidacloprid and permethrin for the dermal control of parasitic insects. See the abstract, and lines 35-40 in column 4 for imidacloprid and lines 1-2 in column 9 where these compounds are disclosed. See also lines 25-34 in column 8.

Instant claims differ from the reference in having different generic scope.

Prior art teaches the combination of imidacloprid and permethrin that the active compounds can be present in the form of a mixture may be synergists with other active compounds such as pyrethroids etc., see lines 5-10 in col. 17. Permethrin is particularly disclosed in lines 21 and 22 in column 18.

Since prior art teaches that imidacloprid is synergistic with various pyrethroids and Dorn et al teaches combination of permethrin and imidacloprid may be synergistic

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one skilled in the art would expect that combination of imidacloprid and permethrin would be synergistic seeing the teaching of prior art.

It would have been obvious to one skilled in the art at the time of invention to prepare additional beneficial composition for controlling insects because prior art teaches control of insects by the same combination of compounds as taught by the prior art. Since the synergistic combination is taught by the prior art therefore there is a motivation to prepare the formulation for controlling insects. The combination would have been a routine experimentation because it was known that synergism exist between these compounds as taught by the prior art.

The data of the combination with chloronicotinylic (imidacloprid) and pyrethroid (permethrin) is disclosed on pages 16-19, Tables 1-4. The data presented is not synergistic. Even if it had been synergistic since prior art teaches synergistic effect of such combinations, one skilled in the art would expect synergism with the combination such as imidacloprid and permethrin because they are most effective agents.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

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**Response to Remarks**

- Arguments were fully considered but are not found persuasive therefore all the rejections are maintained for the same reason as set forth in the previous office action. Data in the specification does not show synergism. Further, synergistic combination would have been obvious to one who is familiar with the art because of the reasons cited above.

**Conclusion**

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER